

JAN 31 2013

510(K) Summary – MAGNIFUSE® Bone Graft

**A summary of Safety And Effectiveness Information
(In accordance with the requirements of 21CFR 807.92)**

November 12, 2012

- I. Company:** Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (732)-578-6697
Fax: (732) 389-3095
Establishment Registration: 1030489
- Contact:** Muriel Ashie
Principal Regulatory Affairs Specialist
- II. Name of Product:**
Proprietary Trade Name: MAGNIFUSE® Bone Graft
Common Name: Demineralized Bone Matrix Allograft
- III. Classification Name(s):** Resorbable Bone Void Filler
Device Classification Panel: Orthopedic
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV, MBP
- IV. Description and Purpose of Application:**
MAGNIFUSE® Bone Graft is comprised of human demineralized cortical bone fibers mixed with non-demineralized cortical bone fibers sealed in an absorbable PGA mesh pouch to form the final product.

The purpose of this 510(k) is to request a change in formulation in MAGNIFUSE® Bone Graft. The predicate device is a combination of demineralized bone matrix in a fiber form and partially demineralized cortical chips while the subject device is a combination of demineralized bone matrix in a fiber form and non-demineralized cortical fibers.

V. Indications for Use:

MAGNIFUSE® Bone Graft is intended for use as a bone graft substitute and bone void filler in bony voids or gaps of the skeletal system (i.e., posterolateral spine and pelvis) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. MAGNIFUSE Bone Graft is resorbed/ remodeled and is replaced by host bone during the healing process.

VI. Identification of the Legally Marketed Predicate Devices Use to Claim Substantial Equivalence:

Predicate Devices: MAGNIFUSE Bone Graft [K082615, SE 10/16/2008];
(Cleared as Grafton II eDBM)
GRAFTON DBM [K051195, SE 12/16/2005]
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Product Code: MQV, MBP

The MAGNIFUSE Bone Graft that is the subject of this 510(k) is substantially equivalent to the previously cleared MAGNIFUSE Bone Graft referenced above.

VII. Summary of Technical Characteristics of Subject Device Compared To Predicate Device

The MAGNIFUSE® Bone Graft that is the subject of this 510(k) is substantially equivalent to the above mentioned predicate MAGNIFUSE Bone graft device with respect to the design features and materials. The predicate and subject MAGNIFUSE devices both consist of human cortical bone allograft tissue contained in a sealed poly(glycolic acid; PGA) mesh pouch. The allograft bone component in both the predicate and subject MAGNIFUSE consists of demineralized bone matrix (DBM) in a fiber form as an osteoinductive component, combined with an osteoconductive cortical bone allograft component, specifically, partially demineralized cortical chips in predicate MAGNIFUSE and non-demineralized cortical fibers in the subject MAGNIFUSE.

Based on similar material composition, similar Indications for Use statement, identical operating principles, identical finished product specifications and equivalent performance in an animal model, the subject MAGNIFUSE Bone Graft, is substantially equivalent to the predicate MAGNIFUSE Bone Graft.

VIII. Performance Data

In vivo studies of both subject and predicate MAGNIFUSE Bone Graft implants in animals showed remodeling and fusion rates comparable to each other and to autograft bone. Osteoinductivity studies in an athymic rat model also showed comparable osteoinductivity scores for the subject and predicate MAGNIFUSE Bone Grafts.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
% Ms. Muriel Ashie
Principal Regulatory Affairs Associate
1800 Pyramid Place
Memphis, Tennessee 38132

Letter dated: January 31, 2013

Re: K123691

Trade/Device Name: MAGNIFUSE® Bone Graft
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: November 26, 2012
Received: December 3, 2012

Dear Ms. Ashie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K123691

Device Name: MAGNIFUSE® Bone Graft

Indications for Use

MAGNIFUSE® Bone Graft (GRAFTON® II eDBM) is intended for use as a bone graft substitute and bone void filler in bony voids or gaps of the skeletal system (i.e., posterolateral spine and pelvis) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. MAGNIFUSE® Bone Graft is resorbed / remodeled and replaced by host bone during the healing process.

Prescription Use X
Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF
NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N. Melkerson
2013.01.31 17:21:00 -05'00'

Director, DOD - K123691